K083502
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PROWESS

510(K) SUMMARY

As required by 21 CFR Part 807.92

MAY - 5 2009

November 19, 2008

1.	**Submitter:**	Prowess, Inc. 5063 Commercial, Suite A & B Concord, CA. 94520
	Contact Person:	Rachel Scarano Regulatory Affairs Manager Prowess, Inc. 5063 Commercial, Suite A & B Concord, CA. 94520 PHONE: (925) 356-0360 FAX: (530) 356-0363
	Device Manufacturer:	Prowess, Inc. 5063 Commercial, Suite A & B Concord, CA. 94520
2.	**Device Trade Name:**	Panther™ RealART
	Classification Name:	Accelerator, Linear, Medical (21 CFR § 892.5050), Class II
	Reg. No.:	2939248
	Common Name:	Radiation Therapy Treatment Planning System
3.	**Predicate Devices:**	Adaptive Targeting™ function of ONCOR Expression™ with COHERENCE Workspace (K060226)

4. Device Description

PANTHER™ RealART is an optional software module to the Prowess radiation therapy planning software for supporting online image-guided radiation therapy. The Panther™ RealART on-line plan adaptation system is composed of a workstation with two Intel Quad-Core Xeon processors (or later versions) running Windows XP operation system (or later versions) and proprietary software that allows the trained users to adjust radiation therapy treatment plans based on the images acquired on the day of treatment with the patient at the treatment position.

The Panther™ RealART software contains 3 components:

a. **Rapid delineation of targets and organs at risk (OAR)** --- The first step of the online correction system is to use robust software and hardware tools to modify the contours rapidly. Tools developed for speeding up contour delineation include: (1) quickly drag and drop planning contours onto the CT of the day, (2) interpolate contours for skipped images, and (3) interactively draw/modify contours.

b. **Segment aperture morphing** --- The segment aperture morphing (SAM) algorithm is designed to calculate the corrections on the position and shape of the beam portals based on the images acquired on-line when the patient is at the treatment position.

c. **Segment weight optimization** --- The segment weight optimization only modifies the segment weights to further improve the original plan by taking advantage of the anatomy revealed by the images of the day.

5. Intended Use

Panther™ RealART is an optional software module to the Prowess Panther™ Radiation Therapy Treatment Planning System family. It is intended to provide online correction on the position and shape of the beam portals based on the images acquired on the treatment day when the patient is at the treatment position.

6. Summary of Technological Considerations

Panther™ RealART, the online adaptive plan option to the existing Prowess treatment planning system, is substantially equivalent to the predicate device. It has the same intended use and similar technical characteristics as the predicate device. It results in equivalent or better quality of treatment plans as compared with the use of predicate device as demonstrated in our field tests.

7. Summary of Comparisons to Predicate Devices

Panther™ RealART adds online, image-guided plan adaptation capabilities to the existing Prowess Panther™ planning system (K032456). It has the same purpose and effects as the predicate device – Adaptive Targeting™ function of ONCOR Expression™ with COHERENCE Workspace (K060226) - utilizing the images of the day to align the radiation beams with the treatment target.

What distinguishes Panther™ RealART from the predicate device is described in detail under Section VIII: Substantial Equivalence Comparison. Unlike in the predicate device, where the patient and treatment target are treated as a rigid body and the treatment couch is shifted to align the target with the beam portals, Panther™ RealART shifts the beam portals and adjusts their shape if the target has deformed. Subsequent dose

calculation is used to verify the dose coverage of the target and the correctness of the on-line correction.

8. Summary of Non-clinical Tests

A Hazard Analysis was completed for Panther RealART. Methods for preventing such hazards were detailed (Section IX). Verification and validation of the software was conducted in house according to the Verification and Validation (V&V) Protocol. The V&V Protocol, and test results are included in Section X of this submission. Functional testing was conducted both in-house and by medical physicists/dosimetrists at the Medical College of Wisconsin. These tests have demonstrated that the RealART option to the Prowess Panther™ treatment planning system has met its specifications, demonstrated substantially equivalent performance to the predicate device, and is safe and effective for its intended use.

9. Summary of Clinical Tests

Although clinical testing is not required to demonstrate substantial equivalence in safety and effectiveness, we elect to conduct testing at the Medical College of Wisconsin using real patient cases. We feel that, no matter how carefully a product is tested in the factory, such testing cannot replace testing in the field. Clinical testing was performed on selected four CT datasets acquired in a total of four fractions from two prostate and one pancreas cases at Medical College of Wisconsin.

10. Labeling

The CD media labeling and User's manual are provided in Section VII of this submission. The entire user's manual in digital format is also included in the software media and can be viewed as part of the on-line help.

Commercial and marketing materials are also included in Section VII.

Product labels comply with 21 CFR 1040.10 and 1040.11 as applicable.

11. Summary of Safety and Effectiveness Information

a. Prowess, Inc. is a registered medical device establishment that meets the requirements of ISO 13485, the Medical Device Directive 93/42/EEC Annex II and 21 CFR 820.

b. The Panther RealART option was designed and implemented according to the established R&D and quality management procedures of Prowess, Inc.

c. The management of the company is committed to the highest standards of Quality Management. The Quality Management System is subject to regular, planned and documented audits by external consultants and by the FDA.

d. A comprehensive Risk Analysis has been conducted. Detailed methods of mitigating these potential risks have been identified by the development and

marketing team, and verified by clinical physicists contracted by Prowess as adequate.

e. The Software has been verified and validated based on established testing plans. The functionalities have been tested by in-house test engineers. In addition to in-house testing, the system was also tested by our beta-site using clinical cases. Documentation of these tests are included in Section X of the submission.

f. Key safety features of Prowess Panther include using a proprietary database for managing important plan data and providing QA tools which allow the user to copy patient treatment plans to a phantom for QA measurements. When communicating with external medical devices used in radiation therapy such as CT, Record & Verify systems, and linear accelerators, Prowess Panther system adheres to the DICOM-RT standard.

g. Steps and precautions for the safe and effective use of the new inverse planning option are detailed in the User Manual. Training by Prowess' physicist is provided as part of the product distribution.

12. Conclusions

Panther™ online plan adaptation option, Panther RealART, is substantially equivalent to the predicate devices. It has the same intended use and similar technical characteristics. It generates equivalent or better quality of treatment plans as compared with the predicate devices as demonstrated in our field tests, and its use does not raise any new, or different issues of safety or effectiveness when compared with the predicates. As demonstrated in the comparison with predicate devices, the use of Panther™ RealART will improve the accuracy of IMRT treatment delivery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2009

Ms. Rachel Scarano
Regulatory Affairs Manager
Prowess, Inc.
5063 Commercial Cir., Suite A & B
CONCORD CA 94520

Re: K083502
Trade/Device Name: Panther™ Real/ART
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: March 24, 2009
Received: March 25, 2009

Dear Ms. Scarano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

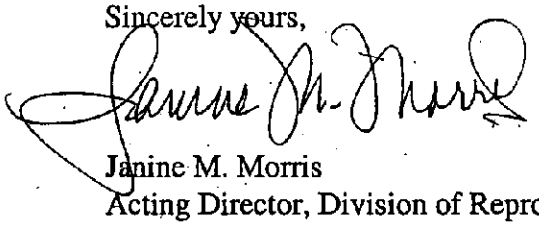
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Tab 3

Indications For Use

510(k) Number (if known): Pending K083502

Device Name: Panther™ RealART

Indications for Use:

Panther™ RealART is used to correct geometric mismatches between radiation beams and the treatment target under on-line image-guidance. The optional software module is part of the family of treatment planning products under the trade name Panther™.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carolyn Neuland for J M Morris

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083502